DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2014

Phase One Medical
% Aditya Sukthankar
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K140884
Trade/Device Name: Symetrex Long Term Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Devices and Accessories
Regulatory Class: II (Special Controls)
Product Code: MSD
Dated: October 27, 2014
Received: October 29, 2014

Dear Aditya Sukthankar,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit/tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140884

Device Name
Symetrex Long Term Hemodialysis Catheter

Indications for Use *(Describe)*

The Symetrex Long Term Hemodialysis Catheter is a symmetric tip dual lumen catheter designed for chronic hemodialysis and apheresis. It may be inserted percutaneously or by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: K 140884

1. Submitter's Identification:

Phase One Medical
35 Pond Park Road
Hingham, MA 02043
Tel: 781-740-0076
Fax: 781-740-0060
Contact: Mr. Adrian Ravenscroft
Engineer

Date Summary Prepared: November 26, 2014

2. Name of the Device:

Symetrex Long Term Hemodialysis Catheter

Device Common Name: Catheter, Hemodialysis, Implanted
Device Classification Name: Blood Access device and accessories
Product Regulation Number: 21 CFR Part 876.5540
Product Code: MSD
Regulatory Class: II (Special Controls)
Classification Panel: Gastroenterology and Urology

3. Predicate Devices' Information:

1) K102043 - Rex Medical UltraStream Chronic Hemodialysis Catheter
2) K123196 - Palindrome™ Precision Symmetric Tip Lumen Catheter

4. Device Description:

The Symetrex Long Term Hemodialysis Catheter is a chronic, 15.5 French, dual lumen, radiopaque catheter made of polyurethane. It has a polyester retention cuff and two female luer adapters. The retention cuff promotes tissue ingrowth to anchor the catheter in the subcutaneous tunnel. The luer adapters are identical in color to indicate the reversibility of this catheter. This catheter features symmetrical side channels with a distal tip configuration designed to separate the intake flow from the output flow in both directions.

5. Intended Use:

The Symetrex Long Term Hemodialysis Catheter is a symmetric tip dual lumen catheter designed for chronic hemodialysis and apheresis. It may be inserted percutaneously or by cut down. Catheters with greater than 37 cm implant length are indicated for femoral placement.

6. Comparison to Predicate Devices:

Attribute	**Symetrex Long Term Hemodialysis Catheter(Subject Device)**	**Rex Medical UltraStream Chronic Hemodialysis Catheter (Predicate Device)**	**Covidien Palindrome (Predicate Device)**
Catheter Type	Implanted Vascular Access	Implanted Vascular Access	Implanted Vascular Access
Intended Use	Hemodialysis and Apheresis	Hemodialysis and Apheresis	Hemodialysis and Apheresis
Lumen Configuration	2 Kidney Shaped Lumens	2 Kidney Shaped Arterial Lumens, 1 Round Venous Lumen	2 Kidney Shaped Lumens
Catheter O.D.	15.5 Fr.	15.5 Fr.	14.5 Fr.
Arterial/Venous Access Lumens	Yes	Yes	Yes
Color Coded Female Luers	No: Arterial and Venous Lumens Interchangeable	Yes: Red (Arterial), Blue (Venous)	Yes: Red (Arterial), Blue (Venous)
Color Coded Clamp on Extensions	Yes	No	No
Suture Wing on Cath. Hub	Yes	Yes	Yes
Catheter Cuff for Tissue In-Growth	Yes	Yes	Yes
Radiopaque Catheter Lumen	20% Barium Sulfate	20% Barium Sulfate	20% Barium Sulfate
Offset Tip for Arterial / Venous Separation	Symmetrical Tip	Stepped Tip	Symmetrical Tip
Hub junction for catheter lumen / extension tubing	Injection Molded, One Piece Hub	Injection Molded, One Piece Hub	Injection Molded, One Piece Hub
Dilator Provided for Catheter Insertion	10-12 Fr. Dilator, 12-14 Fr. Dilator	16 Fr. Dilator	12 Fr. Dilator, 14 Fr. Dilator
Tunneling Tool provided for Catheter Insertion	Yes	Yes	Yes
Injection Sites supplied with Catheter	Yes : Qty 2 Latex Free Injection Sites	Yes : Qty 2 Latex Free Injection Sites	Yes : Qty 2 Latex Free Injection Sites
Priming Volume Printed on Female Luers	Yes: Priming Volume Printed on I.D. Tag	Yes: Priming Volume Printed on I.D. Tag	Yes: Priming Volume Printed on Female Luer
Catheter Identification and Reference size printed on Catheter Hub	Yes: Name of Catheter Printed on Hub	Yes: Name of Catheter Printed on Hub	Yes: Name of Catheter Printed on Clamp

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

Comparative functional testing to the predicated devices was performed based on ISO 10555-1 and the FDA's Implanted Blood Access Devices for Hemodialysis - Draft Guidance for Industry and Food and Drug Administration Staff. Material testing also included ISO 10993 Biocompatibility Testing. Symetrex Long Term Hemodialysis Catheter conforms to the special controls mandated by 21 CFR 876.5540. Testing results revealed the subject device to be substantially equivalent to the predicate device.

8. Discussion of Clinical Tests Performed:

Not applicable as there are no new indications for use which must be supported by clinical data.

9. Conclusions:

The subject device, the Symetrex Long Term Hemodialysis Catheter, has the same intended use as the predicate devices, the Rex Medical UltraStream Chronic Hemodialysis Catheter (K102043) and the Palindrome™ Precision Symmetric Tip Dual Lumen Catheter (K123196). Bench testing and non-clinical testing supplied within our submission demonstrates that there are not any differences in their technological characteristics thereby not raising any new questions of safety and effectiveness. Therefore, the Symetrex Long Term Hemodialysis Catheter is substantially equivalent to the predicate devices, the Rex Medical UltraStream Chronic Hemodialysis Catheter (K102043) and the Palindrome™ Precision Symmetric Tip Dual Lumen Catheter (K123196).